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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,578	12/04/2000	Muriel Keller	BC-0181-P06	5244
24994	7590	02/24/2004	EXAMINER	
GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	6

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/729,578

Applicant(s)

KELLER ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-12 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 13-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1, 2, and 13-21** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bischof (5,865,785). Bischof discloses a system and method of using the system for blood processing wherein whole blood is collected from a patient via a phlebotomized tubing flow path and delivered to a centrifuge for separation into its components (red blood cells (RBC), platelets, a buffy coat (WBC), and plasma). Bischof discloses that the system may be used in a continuous manner. It is well known that whole blood separates into its components upon centrifugation. It is well known that the difference in the densities of the blood components results in RBC being disposed at the radially outward most position, a buffy

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coat thereafter, and the plasma defining the innermost position. Platelets will be mainly in the buffy coat region. Therefore, since the Bischof system and method of using acts in a continuous manner, it is seen to be inherent that the whole blood will separate into RBC and platelets in a continuous manner. As shown in the flow chart of figure 1, the RBC and platelets (PRP) are all separated and may be collected in separate containers. Further, as shown in figure 2, it is implied or inherent that at least some of the platelets and at least some of the RBC are removed from the centrifuge (in its first stage chamber 16) at the same time. Bischof also teaches that plasma is separated and may be collected (see figure 2). The centrifuge or processing vessel inherently has a rpm rate for spinning and may be increased for spinning and separating the whole blood and decreased for collection.

If applicant does not agree that Bischof anticipates the claimed invention with respect to the step of removing at least some of the platelets and at least some of the RBC are from the centrifuge at the same time, it is the position of the examiner that the step is obvious. As noted above, Bischof implies at the step in its first stage chamber (shown by reference number 16) that at least some of the platelets and at least some of the RBC are removed from the centrifuge at the same time. It would have been obvious to remove, and collect if desired, RBC and platelets after a first separation (i.e. the first stage 16 in figure 2).

Claims **2, 20 & 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischof in view of Latham, Jr. et al. (5,607,579). Bischof discloses the invention

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substantially as claimed, see rejection supra. Bischof, however, fails to disclose specifically that the hematocrit is at least 75%, an AC ratio of about 6-16 is established, and the hematocrit and AC ratio are maintained.

Latham, Jr. et al. teaches of a blood separation system and method where whole blood is separated in an apheresis method. The system includes sensors that determine the AC ratio (referred by Latham, Jr. to be ACD ratio) and a hematocrit percentage for optimum function. (Col. 3, line12-col. 5, line 63; figs. 8A-B). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the system and method of Bischof to incorporate the sensors and steps of monitoring and maintaining the AC ratio and hematocrit to ensure the optimum treatment conditions for the patient/donor.

### ***Allowable Subject Matter***

Claims 3-12 are allowed over the prior art of record. The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The subject matter not found was the step of performing a red blood cell collection set-up phase that includes establishes a packing factor of at least about 11 within separated red blood cells in the blood processing vessel in combination with the other elements (or steps) in the claims.

### ***Response to Arguments***

Applicant's arguments filed 12/09/03 have been fully considered but they are not persuasive. Applicant argues that Bischof does not teach of plasma extraction and RBC

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extraction from the blood processing vessel occurring contemporaneously, but rather to a finishing device that completes platelet processing outside the centrifugal field after RBC separation. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *plasma extraction and RBC extraction*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim only recites "*removing at least some of said platelets and some of said red blood cells*" from the blood processing vessel. It is not claimed that extraction of platelets and RBC but rather only a portion of or "at least some of" the platelets and RBC be removed from the separation device. As noted above in the rejection, figure 2 shows or implies that at least some of the platelets and at least some of the RBC are removed from the centrifuge (in its first stage chamber 16) at the same time, regardless of what the next step for the platelets is. Bischof does further teach of a finishing device for the platelets, however, that does not occur until after a first separation and removal of at least some platelets has been performed with the disclosed system and method.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

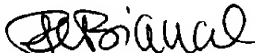
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 20<sup>th</sup>, 2004

  
Patricia M Bianco  
Primary Examiner  
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